4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Ethical and Regulatory Challenges in the Development of Pediatric Medical Countermeasures; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Pediatric Therapeutics, is announcing a public workshop entitled "Ethical and Regulatory Challenges in the Development of Pediatric Medical Countermeasures." There is a critical need for pediatric research on medical countermeasures to ensure that these products are safe and effective in the pediatric population. The challenges to developing and evaluating drugs, biologics, and devices for children in the medical countermeasure context are complex and need to be better understood by ethicists, researchers, policymakers, and the general public. The purpose of the public workshop is to provide a forum for careful consideration of scientific, ethical, and regulatory issues confronting FDA and other stakeholders in the area of medical countermeasures and public health preparedness.

Date and Time: The public workshop will be held on February 15, 2012, from 8:30 a.m. to 5 p.m and February 16, 2012, from 8:30 a.m to 3 p.m.

Location: The public workshop will be held at the Rockville Hilton Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Cindy de Sales, 240-316-3207, FAX: 240-316-3201, email: cindy@tepgevents.com.

Registration: Please use the following Web site to register online: http://www.contractmeetings.com. Alternatively, you can email or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by February 1, 2012. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Cindy de Sales (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop will include plenaries and breakout sessions on the ethical and regulatory challenges in the development of medical countermeasures for the pediatric population. Topics of the breakout sessions will include: (1) Institutional Review Board preparedness to review study protocols relevant to pediatric medical countermeasures; (2) potential scientific and ethical justifications for conducting pre-event pediatric medical countermeasures research; (3) leveraging new technologies to develop pediatric medical countermeasures; and (4) risk communication related to pediatric treatment and research during public health emergencies. The workshop also will include discussion of a number of case studies to facilitate discussion of the challenges of pediatric medical countermeasure development and deployment.

Transcripts: Transcripts of the public workshop may be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, approximately 15 working days after the

public workshop at the cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at http://www.regulations.gov, Docket No. FDA-2011-N-0002**.** Transcripts may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: January 12, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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